seriousness of the public health and social problems associated with the abuse of methcathinone is assessed to be especially serious. On the basis of this and the assessment of its therapeutic usefulness, it is recommended that methcathinone be included in Schedule I of the Convention on Psychotropic Substances, 1971.

*Zipeprol*

1. Substance identification

Zipeprol (INN; CAS 34758–83–3), chemically o-(α-methoxybenzyl—4-(β-methoxyphenethyl)-1-piperazineethanol, is also know as Antituxil-Z, Carm-3024, Chilvax, Delaviral, Dovavixin, Jactus, Eritos, Mirsol, Ogyline, Rospilene, Respirase, Respirax, Sanotus, Sentus, Silentos, Sousibim, Talasa, Tusigen, Tussiflex and Zitoxil. Zipeprol has three asymmetric carbon atoms in the molecule, so that eight stereoisomeric forms are possible.

2. Similarity to already known substances and affects on the central nervous system

In laboratory animals, zipeprol has been shown to have an antitussive activity weaker than codeine and comparable to dextromethorphan. Its pharmacological properties are different from those of opioid antitussives, such as codeine, in that zipeprol has anti-cholinergic activities. It also does not produce respiratory depression, bile duct constriction or constipation, which are often associated with narcotic antitussives.

Unlike opioids, zipeprol is essentially devoid of analgesic activity, but at higher doses, zipeprol acts like a weak opioid agonist. Zipeprol showed a bi-phasic effect in competing for binding sites in rat brain homogenates.

3. Dependence potential

In rats, lower doses of zipeprol amplify some opioid withdrawal manifestations whereas at higher doses it suppresses several morphine withdrawal symptoms. In the monkey, zipeprol suppresses morphine abstinence. Zipeprol is assessed to have a moderate dependence potential.

4. Actual abuse and/or evidence of likelihood of abuse

There have been a number of reports on the abuse of zipeprol from Brazil, Chile, Italy, Mexico, the Republic of Korea, Switzerland, and the former Yugoslavia. These reports suggest that its sedative, hallucinatory and euphorigenic effects, and its ability to suppress some signs of opioid withdrawal at high doses, may be the reasons for its abuse. Over-the-counter distribution of zipeprol preparations may have contributed to its widespread abuse in some places. Taking this into account, zipeprol is assessed to have a moderate abuse liability.

Adverse health consequences of zipeprol abuse include seizures, hallucinations, confusion and amnesia. Dose escalation is not uncommon and fatal cases from intoxication were reported from several countries. The tablet form has been used for intravenous administration.

5. Therapeutic usefulness

A number of clinical studies have demonstrated the therapeutic efficacy of zipeprol in the treatment of cough. The therapeutic usefulness of zipeprol is assessed to be within the range between little to moderate.

6. Recommendation

Although zipeprol is a weak opioid agonist at high doses, its toxicity, hallucinogenic and other psychotropic effects constitute a significant element in its abuse. It is therefore appropriate to consider its control under the Convention on Psychotropic Substances, 1971.

Based on the available data concerning its pharmacological and toxicological profile, dependence potential and likelihood of abuse, the degree of seriousness of the public health and social problems associated with the abuse of zipeprol is assessed to be substantial. On the basis of this and the assessment of its therapeutic usefulness, it is recommended that zipeprol be included in Schedule II of the Convention on Psychotropic Substances, 1971.

## III. Discussion

Although WHO has made specific scheduling recommendations for each of the drug substances, CND is not obliged to follow the WHO recommendations. Options available to CND include:

(1) Acceptance of the WHO recommendations;

(2) acceptance of the recommendations to control but control the drug substance in a schedule other than that recommended; or

(3) reject the recommendations entirely.

Methcathinone, etryptamine and aminorex, are controlled under the CSA in Schedule I. The proposed international drug scheduling actions, if adopted by CND, will result in no greater degree of control of these substances than are currently applied domestically. Flunitrazepam is controlled domestically in Schedule IV of the CSA; additional controls may be necessary if the United Nations moves this substance to Schedule III of the Convention. Brotizolam, mesocarb, and zipeprol are neither controlled domestically nor currently marketed for medical use in the United States. In order to comply with obligations under the Convention, these three substances would have to be controlled under the CSA if the United Nations endorses the WHO recommendations.

FDA, on behalf of the Secretary of HHS, invites interested persons to submit comments on the United Nations notifications concerning these seven drug substances. FDA, in cooperation with the National Institute on Drug Abuse, will consider the comments on behalf of HHS in evaluating the WHO scheduling recommendations. Then, pursuant to section 811(d)(2)(B) of the CSA, HHS will recommend to the Secretary of State what position the United States should take when voting on the recommendations at the CND meeting in March 1995.

## IV. Submission of Comments and Opportunity for Public Meeting

Interested persons may, on or before February 9, 1995, submit to the Dockets Management Branch (address above) written comments regarding this notice. FDA does not presently plan to hold a public meeting. If any person believes that, in addition to its written comments, a public meeting would contribute to the development of the U.S. position on any of these two substances, a request for a public meeting and the reasons for such a request should be sent to Nicholas P. Reuter (address above) on or before January 30, 1995. The short time period for the submission of comments and requests for a public meeting is needed to assure that HHS may, in a timely fashion, carry out the required action and be responsive to the United Nations. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch (address above) between 9 a.m and 4 p.m., Monday through Friday.

Dated: January 17, 1995.

**William K. Hubbard,**

*Interim Deputy Commissioner for Policy.*

[FR Doc. 95–1553 Filed 1–19–95; 8:45 am]

BILLING CODE 4160–01–F

## Advisory Committees; Notice of Meetings

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1–800–741–8138 or 301–443–0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The

hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

**MEETINGS:** The following advisory committee meetings are announced:

### Psychopharmacologic Drugs Advisory Committee

*Date, time, and place.* February 6, 1995, 8:30 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

*Type of meeting and contact person.* Open public hearing, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5 p.m.; Michael A. Bernstein, Center for Drug Evaluation and Research (HFD–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5521, or FDA Advisory Committee Information Hotline, l–800–741–8l38 (301–443–0572 in the Washington, DC area), Psychopharmacologic Drugs Advisory Committee, code 12544.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of psychiatry and related fields.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 30, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

*Open committee discussion.* The committee will discuss the safety and effectiveness of Depakote® tablets (divalproex sodium tablet), new drug application (NDA) 20–320, Abbott Laboratories, for use in the treatment of manic episodes associated with bipolar disorder.

### Subcommittee Meeting of the National Task Force on Aids Drug Development/Drug Discovery Issues

*Date, time, and place.* February 6, 1995, 8:30 a.m., National Institutes of Health, Bldg. 31, rm. 6C–8, 9000 Rockville Pike, Bethesda, MD; and February 7, 1995, 8:30 a.m., Executive Plaza North, conference room G, 6130 Executive Plaza Blvd., Bethesda, MD.

*Type of meeting and contact person.* Open subcommittee discussion, February 6, 1995, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; open subcommittee discussion, February 7, 1995, 8:30 a.m. to 4 p.m.; open public hearing, 4 p.m. to 5 p.m., unless public participation does not last that long; Jean H. McKay or Kimberley M. Miles, Office of AIDS and Special Health Issues (HF–12), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–0104, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), National Task Force on AIDS Drug Development, code 12602.

*General function of the task force.* The National Task Force on AIDS Drug Development shall identify any barriers and provide creative options for the rapid development and evaluation of treatments for human immunodeficiency virus (HIV) infection and its sequelae. It also advises on issues related to such barriers, and provides options for the elimination of these barriers.

*Open subcommittee discussion.* On February 6, 1995, the subcommittee will present, hear, and discuss issues on the use of and access to available animal models in the drug discovery/development process and examine the prospects for the development of new models for such purposes. On February 7, 1995, the subcommittee will identify mechanisms for rapid development and sharing of screening assays and to determine the feasibility of an expanded drug-screening effort, related to the identification of potential therapies for HIV disease.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the task force. Those desiring to make formal presentations should notify the contact person before February 1, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

### Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (Ranch Hand Advisory Committee)

*Date, time, and place.* February 13 and 14, 1995, 9 a.m., Holiday Inn, 400 Arch St., Philadelphia, PA.

*Type of meeting and contact person.* Open committee discussion, February 13, 1995, 9 a.m. to 5:30 p.m.; open public hearing, February 14, 1995, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5:30 p.m.; Ronald F. Coene, National Center for Toxicological Research (HFT–10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3155, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Ranch Hand Advisory Committee, code 12560.

*General function of the committee.* The committee shall advise the Secretary and the Assistant Secretary for Health concerning its oversight of the conduct of the Ranch Hand Study by the Air Force and other studies in which the Secretary or the Assistant Secretary for Health believes involvement by the advisory committee is desirable.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before January 31, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their comments.

*Open committee discussion.* The committee will continue the review of the chapters of the draft report presenting the results of the 1992 health examination of participants in the Air Force Health Study entitled ''An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides.'' This review will include chapters on: Neoplasia, neurology, psychology, gastrointestinal, cardiovascular, hematologic, endocrinologic, and immunologic data, as well as information on quality control, statistical methods, and covariate associations and the summary chapter on conclusions and future directions. A final agenda will be available February 6, 1995, from the contact person.

### Oncologic Drugs Advisory Committee

*Date, time, and place.* February 14, 1995, 8 a.m., Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD.

*Type of meeting and contact person.* Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 4:30 p.m.; Adele S. Seifried, Center for Drug Evaluation and Research (HFD–9), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of cancer.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 10, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

*Open committee discussion.* The committee will discuss in the order listed: (1) NDA 50–718, Dox-SL (pegylated liposomal doxorubicin hydrochloride, Liposome Technology, Inc.) for AIDS-related Kaposi's Sarcoma in patients who have failed prior systemic combination chemotherapy either due to progression of disease or unacceptable toxicity; and (2) NDA 20–515, Zoladex® (goserelin acetate implant, Zeneca Pharmaceuticals Group) for palliative treatment of advanced breast cancer in pre- and perimenopausal women.

### Cardiovascular and Renal Drugs Advisory Committee

*Date, time, and place.* February 23 and 24, 1995, 8:30 a.m., National Institutes of Health, Clinical Center, Bldg. 10, Jack Masur Auditorium, 9000 Rockville Pike, Bethesda, MD. Parking in the Clinical Center visitor area is reserved for clinical center patients and their visitors. If you must drive, please use an outlying lot such as Lot 41B. Free shuttle bus service is provided from Lot 41B to the Clinical Center every 8 minutes during rush hour and every 15 minutes at other times.

*Type of meeting and contact person.* Open public hearing, February 23, 1995, 8:30 a.m. to 9:30 a.m., unless public participation does not last that long; open committee discussion, 9:30 a.m. to 5:30 p.m.; open committee discussion, February 24, 1995, 8:30 a.m. to 5:30 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFD–110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 419–259–6211, Valerie M. Mealy, Advisors and Consultants Staff, 301–443–4695, or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Cardiovascular and Renal Drugs Advisory Committee, code 12533.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in cardiovascular and renal disorders.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 6, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

*Open committee discussion.* On February 23, 1995, the committee will discuss: (1) NDA 09–218, S–76, Dupont Merck, Coumadin® (warfarin), for prevention of death, recurrent myocardial infarction, and thromboembolic events, such as stroke after myocardial infarction; and (2) NDA 20–444, Burroughs Wellcome Co., Flolan® (epoprostenol), for treatment of primary pulmonary hypertension. On February 24, 1995, the committee will discuss antianginal guidelines.

### Endocrinologic and Metabolic Drugs Advisory Committee

*Date, time, and place.* February 23 and 24, 1995, 8:30 a.m., Holiday Inn Silver Spring, Plaza Ballroom, 8777 Georgia Ave., Silver Spring, MD.

*Type of meeting and contact person.* Open public hearing, February 23, 1995, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; open public hearing, February 24, 1995, 8:30 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 4 p.m.; Kathleen R. Reedy, Center for Drug Evaluation and Research, Advisors and Consultants Staff, HFD–9, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5455, FAX (301–443–0699), or FDA Advisory Committee Information Hotline, 1–800–741–8138 (301–443–0572 in the Washington, DC area), Endocrinologic and Metabolic Drugs Advisory Committee, code 12536.

*General function of the committee.* The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in endocrine and metabolic disorders.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before February 16, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

*Open committee discussion.* On February 23, 1995, the committee will hear presentations and discuss data submitted regarding the safety and efficacy of sermorelin acetate, NDA 20–443 (Geref®, Serono), for a growth hormone insufficiency indication. On February 24, 1995, the committee will discuss nilutamide, NDA 20–169 (Anandron®, Roussel Uclaf), for a prostate cancer indication.

### Board of Tea Experts

*Date, time, and place.* February 27 and 28, 1995, 10 a.m., New York Regional Laboratory, rm. 700, 850 Third Ave., Brooklyn, NY.

*Type of meeting and contact person.* Open public hearing, February 27, 1995, 10 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 4:30 p.m.; open committee discussion, February 28, 1995, 10 a.m. to 4:30 p.m.; Faith F. Lim, New York Regional Laboratory, Food and Drug Administration, 850 Third Ave., Brooklyn, NY 11232, 718–965–5730, or FDA Advisory Committee Information Hotline, 1–800–8138 (301–443–0572 in the Washington, DC area), Board of Tea Experts, code 12601.

*General function of the board.* The board advises on establishment of uniform standards of purity, quality, and fitness for consumption of all tea

imported into the United States under 21 U.S.C. 42.

*Agenda—Open public hearing.* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

*Open board discussion*. The board will discuss and select tea standards.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

The Commissioner approves the scheduling of meetings at locations outside of the Washington, DC, area on the basis of the criteria of 21 CFR 14.22 of FDA's regulations relating to public advisory committees.

Dated: January 13, 1995.

**Linda A. Suydam,**

*Interim Deputy Commissioner for Operations.*

[FR Doc. 95–1552 Filed 1–19–95; 8:45 am]

**BILLING CODE 4160–01–F**

## Health Care Financing Administration

## Privacy Act of 1974; System of Records

**AGENCY:** Department of Health and Human Services (HHS), Health Care Financing Administration (HCFA).

**ACTION:** Notice to propose a name change, purpose change, and the addition of new routine uses for an existing system of records.

**SUMMARY:** HCFA is proposing to amend the system notice for the ''Supplemental Medical Insurance'' (SMI) Accounting Collection and Enrollment System (SPACE),'' System No. 09–70–0505, by revising the system name, revising the purpose, and by adding new routine uses. Also, sections of this notice have been updated to reference current addresses and appropriate HCFA components.

HCFA is proposing to change the system name to better reflect the current function of the SPACE system, which now processes Medicare premium billing information for both Part B, SMI, and Part A, HI. The proposed new name is ''Supplementary Medical Insurance (SMI) and Hospital Insurance (HI) Premium Accounting, Collection and Enrollment System (SPACE).'' Despite the amendment to the system name, the acronym SPACE, which refers to this system, will not be changed.

The purpose of this system of records is being updated to include beneficiaries whose HI benefit premiums are paid by a State Medicaid agency, the U.S. Office of Personnel Management (OPM), or a formal third party group (the latter defined in 42 CFR section 408.80 through section 408.92). The purpose originally only references those beneficiaries whose SMI was paid by these named parties.

HCFA is also proposing to add routine uses, which permit the disclosure of data without the prior written consent of an individual, when the use of a record is for a purpose which is compatible with the purpose for which the record was collected. The proposed new routine uses would permit the disclosure of information to the following parties: OPM, formal third party groups, contractors in connection with the maintenance of automated data processing (ADP) software, and an individual or organization for research. (**SEE SUPPLEMENTARY INFORMATION**)

**EFFECTIVE DATES:** HCFA filed an altered system report with the Chair of the House Committee on Government Operations, the Chair of the Senate Committee on Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on January 13, 1995. To ensure that all parties have adequate time in which to comment, the revised system of records, including routine uses, will become effective 40 days from the publication of this notice or from the date it is submitted to OMB and the Congress, whichever is later, unless HCFA receives comments which require alterations to this notice.

**ADDRESSES:** Please address comments to Richard A. DeMeo, HCFA Privacy Act Officer, Office of Customer Relations and Communications, Office of Beneficiary Services, Health Care Financing Administration, Room 2–H–4 East High Rise Building, 6325 Security Boulevard, Baltimore, Maryland 21207–